DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

PETITION

MAY 4 1998

Re: IVOMEC® EPRINEX™ Pour-On for
Beef and Dairy Cattle
Docket No.: 97E-0308

#12

The Honorable Bruce Lehman
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks
Box Pat. Ext.
Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Commissioner Lehman:

This is in regard to the application for patent term extension for U.S. Patent No. 4,427,663, filed by Merck &Co., Inc., under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for IVOMEC® EPRINEX™ Pour-On for Beef and Dairy Cattle, the animal drug product claimed by the patent.

The total length of the regulatory review period for IVOMEC® EPRINEX™ Pour-On for Beef and Dairy Cattle is 2,492 days. Of this time, 2,475 days occurred during the testing phase and 17 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 512(j) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: June 22, 1990.

   FDA has verified the applicant's claim that the date the investigational new animal drug application became effective was on June 22, 1990.

2. The date the application was initially submitted with respect to the animal drug product under subsection 512(b) of the Federal Food, Drug, and Cosmetic Act: March 31, 1997.

   The applicant claims March 27, 1997, as the date the New Animal Drug Application (NADA) for IVOMEC® EPRINEX™ Pour-On for Beef and Dairy Cattle (NADA 141-079) was initially submitted. However, a review of FDA records reveals that the date of FDA's official acknowledgement letter assigning a number to the NADA was March 31, 1997, which is considered to be the initially submitted date for the NADA.

3. The date the application was approved: April 16, 1997.

FDA has verified the applicant's claim that NADA 141-079 was approved on April 16, 1997.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Stuart L. Nightingale, M.D.
Associate Commissioner
for Health Affairs

cc: Mollie M. Yang
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